

Appl. No. 10/799,016
Amdt. dated March 29, 2007
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1645

PATENT

REMARKS/ARGUMENTS

With this amendment, claims 35, and 38-50 are pending. Claims 1-34, 36, and 37 are cancelled. For convenience, the Examiner's rejections are addressed in the order presented in a November 8, 2006 Office Action.

I. Status of the claims

Claim 35 is amended to recite wherein the α -2,3-sialyltransferase polypeptide comprises the amino acid sequence of residues 1-328 of SEQ ID NO:2 or an amino acid sequence that shares at least 95% identity with amino acid residues 1-328 of SEQ ID NO:2. Claim 38 was similarly amended and recites amino acid residues 1-430. Support for these amendments is found throughout the specification, for example, at page 4, lines 17-20 and page 8, lines 26-30. These amendments add no new matter.

II. Objections to the specification

The Office Action objects to the presence of hyperlinks in the specification. In order to expedite prosecution, the specification is amended to remove hyperlinks. In view of the above amendments, withdrawal of the specification and drawing objections is respectfully requested.

III. Rejections under 35 U.S.C. §112, first paragraph, written description

Claims 35-50 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. According to the Office Action, the specification does not provide description of polypeptides with at least 90-95% identity to SEQ ID NO:2. The Office Action alleges that those of skill would not recognize that the inventors had possession of the claimed invention at the time of filing.

The Office Action indicates that the written description rejection can be obviated by amending the claims to recite "wherein the α -2,3-sialyltransferase polypeptide comprises the amino acid sequence of residues 1-328 of SEQ ID NO:2 or an amino acid sequence that shares at

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least 95% identity with amino acid residues 1-328 of SEQ ID NO:2." *See, i.e.*, Office Action at page 4. Applicants have amended claims 35 and 38 as suggested in the Office Action in order to expedite prosecution. It is Applicants' understanding that the amended claims overcome the rejections for alleged lack of written description. In view of these amendments and remarks, withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

IV. Rejections under 35 U.S.C. §102(b) and §102(e)

Claims 35-39 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Gilbert *et al.* *J. Biol. Chem.* 271:28217-28276 (1996) and under 35 U.S.C. §102(b) by Paulson *et al.* (U.S. Patent No. 6,399,336).

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found...in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, in order to anticipate, the cited reference must contain every element of the claims at issue.

Applicants respectfully traverse the rejection and submit that, as amended, the claims are not anticipated by the cited references. Moreover, the Office Action indicates that the anticipation rejections can be obviated by amending the claims to recite "wherein the α -2,3-sialyltransferase polypeptide comprises the amino acid sequence of residues 1-328 of SEQ ID NO:2 or an amino acid sequence that shares at least 95% identity with amino acid residues 1-328 of SEQ ID NO:2." *See, i.e.*, Office Action at page 5. In view of these amendments and remarks, withdrawal of the rejection under 35 U.S.C. §102 is respectfully requested.

V. Rejections for alleged obviousness-type double patenting

Claim 35-47 and 49-50 are rejected as allegedly unpatentable under the judicial doctrine of obviousness type double patenting over claims 1-15 of U.S. Patent No. 6,709,834. In order to expedite prosecution of this application, Applicants submit a terminal disclaimer of the term of a patent granted on the instant application over U.S. Patent No. 6,709,834. Applicants

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note that the filing of a terminal disclaimer to obviate a rejection based on non-statutory double patenting is not an admission of the propriety of the rejection. See, MPEP §804.02.

Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims 35-40 are rejected for alleged obviousness-type double patenting over claims 43-46 of USSN 10/821,573, now US Patent No. 7,192,756 (the '756 patent), to be issued March 2007. Applicants respectfully traverse the rejection. The '756 patent claims CstII proteins that are encoded by a nucleic acid that is amplified from a *Campylobacter* genome using SEQ ID NOs:46 and 47 as the amplification primers. The present claims are directed to CstI proteins from *Campylobacter* bacteria. Applicants provide data that SEQ ID NOs:46 and 47 of the '756 patent will not amplify a nucleic acid from a *Campylobacter* genome that encodes the claimed proteins. Exhibit A provides alignments of the nucleic acid sequence of SEQ ID NO:1 from the present application with the nucleic acid sequence of SEQ ID NO:46 and the reverse complement of SEQ ID NO:47 from the '756 patent. SEQ ID NO:46 aligns poorly near the 5' end of SEQ ID NO:1 and substantial gaps are required for the alignment. Moreover, any amplified product would not include the initiating ATG codon. The reverse complement of SEQ ID NO:47 aligns poorly to SEQ ID NO:1, beginning at about nucleotide 742, and also requires substantial gaps to produce an alignment. Even if the sequence alignment and complementation was sufficient to allow hybridization and amplification of a nucleic acid product, that product would end at about nucleotide 797, or about encoded amino acid 265 of the claimed CstI polypeptides. The amended claims are directed to CstI polypeptides comprising 1-328 or 1-430 amino acids of SEQ ID NO:2 and proteins with 95% identity to those sequences. Thus, the '756 patent primers (SEQ ID NO:46 and 47) cannot be used to produce a nucleic acid that would encode the claimed functional CstI polypeptides. The polypeptides claimed by the present application and the '756 patent are, therefore, patentably distinct and this rejection for alleged obviousness-type double patenting should be withdrawn.

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VI. Rejections under 35 U.S.C. §112, second paragraph

Claims 35-50 are rejected because the phrase "over the entire length" is allegedly indefinite. Applicants respectfully traverse the rejection and submit that, as amended, the claims are not indefinite. Moreover, the Office Action indicates that the rejections for alleged indefiniteness can be obviated by amending the claims to recite "wherein the α -2,3-sialyltransferase polypeptide comprises the amino acid sequence of residues 1-328 of SEQ ID NO:2 or an amino acid sequence that shares at least 95% identity with amino acid residues 1-328 of SEQ ID NO:2." See, i.e., Office Action at page 7. In view of these amendments and remarks, withdrawal of the rejection for alleged indefiniteness is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,


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Attachments
BLK:blk
60981916 v1

Needle

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EMBOSS Align Results

Needle Results	
Matrix	Blosum62
Open gap penalty	10.0
Gap extension penalty	0.5
Needle output	needle-20070308-23144402448256.output
SUBMIT ANOTHER JOB	

```
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# Align_format: srspair
# Report_file: /ebi/extern/old-work/needle-20070308-23144402448256.output
#####
```

```
#=====
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# 1: seq 1 from present app
# 2: rev 47 from '756 patent
# Matrix: EBLOSUM62
# Gap_penalty: 10.0
# Extend_penalty: 0.5
#
# Length: 1293
# Identity: 28/1293 ( 2.2%)
# Similarity: 28/1293 ( 2.2%)
# Gaps: 1252/1293 (96.8%)
# Score: 110.0
#
#
#=====
```

```
seq      1 atgacaaggactagaaatggaaaatgaactcattgttagtaaaaaatgca      50
rev      1
seq     51 aaatataatcatagcaggaaatggacctagcctaaaaaatattaattata      100
rev      1
seq    101 aaagactgcctagagaatatgatgttttttaggtgtaaccagtttttttt      150
rev      1
seq    151 gaagataagtattatttttaggaaaaaagattaaagcagtattttttaatcc      200
rev      1
seq    201 tgggtgtttttttacaacagtatcacactgcaaaacaacttataactaaaaa      250
rev      1
seq    251 atgagtatgaaataaaaaaatatttttttgcctctacatttaatttaacctttt      300
rev      1
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EXHIBIT

A

Needle

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seq	301	attgaaagcaatgattttttacatcaattttataattttttcccgatgc	350
rev	1		0
seq	351	aaaacttggtatgaagttattgaaaaccttaagaattttatgcttata	400
rev	1		0
seq	401	aaaaatacaatgaaattttatttcaataaaagaattacttcgggcgtctat	450
rev	1		0
seq	451	atgtgtgcaattgctattgcattaggatataaaaccatctatttatgtgg	500
rev	1		0
seq	501	cattgatttttatgaaggagatgttatctatccttttgagctatgagta	550
rev	1		0
seq	551	caaataataaaaacaatctttcctggaataaaagatttcaaaccttcaaat	600
rev	1		0
seq	601	tgtcattctaaggaatacgatatagaagcattaaaattgttaaaatcaat	650
rev	1		0
seq	651	atacaaagttaatatctacgcattgtgtgatgattctatttcggcaaate	700
rev	1		0
seq	701	attttcctttatcaatttaaratttaataacaatttcactttagaaaaataag	750
rev	1		9
seq	751	cataataattctataaatgatattttattgactgataataactcctggcgt	800
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seq	801	aagtttttataaaaatcaacttaagctgataataaaattatgcttaatt	850
rev	42		41
seq	851	tttataatattcttcattctaaagataatttaatacaatttttaaacaaa	900
rev	42		41
seq	901	gaaattgcggtatttaaaaaacaaaccactcaacgagctaaagcaagaat	950
rev	42		41
seq	951	ccaaaaccatctatcctataaaactaggacaagctttgattataaattcta	1000
rev	42		41
seq	1001	aaagtgtattagggtttttatctttaccttttataatattaagtatcggt	1050
rev	42		41
seq	1051	atttcacataaacaagaacaaaaggcttataaatttaagtaaaagaaaaa	1100
rev	42		41
seq	1101	tccaaatttagctttaccccttttagaaacttatcctgattataatgaag	1150

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rev	42		41
seq	1151	ctttaaagaaaaagaatgttttacttataaattaggagaagaatttata	1200
rev	42		41
seq	1201	aaagctggtaagaattggtatggggaggggtatatcaaatttatattcaa	1250
rev	42		41
seq	1251	agatgttcctagggttgaagagagagtttgagaaaggggaataa	1293
rev	42		41

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Needle

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EMBOSS Align Results

Needle Results

Matrix: Blosum62
 Open gap penalty: 10.0
 Gap extension penalty: 0.5
 Needle output: needle-20070308-23114566849720.output

SUBMIT ANOTHER JOB

#####

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 # Align_format: srepair
 # Report_file: /ebi/externserv/old-work/needle-20070308-23114566849720.output
 #####

#=====

#

Aligned_sequences: 2
 # 1: seq 1 from present application
 # 2: seq 46 from '756 patent
 # Matrix: EBLOSUM62
 # Gap_penalty: 10.0
 # Extend_penalty: 0.5

#

Length: 1293

Identity: 28/1293 (2.2%)

Similarity: 28/1293 (2.2%)

Gaps: 1252/1293 (96.8%)

Score: 130.0

#

#

#=====

```

seq          1 atgacaaggactagaatggaaaaatgaactcattgtagtaaaaaatgca      50
                      |.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|
seq          1                      CTTAGGAGGT---CATATGAA      18

seq          51 aaatataatcatagcaggaaatggacctagcctaaaaaatattaattata    100
                      |||.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|.|
seq          19 AAAAGTTATTATTGCTGGAATG                                41

seq          101 aaagactgcctagagaatatgatgtttccagggtgaaccagtttttttt    150

seq          42                                                              41

seq          151 gaagataagtattatttaggaaaaaagattaaagcagtattttttaatcc    200

seq          42                                                              41

seq          201 tgggtgtctttttcacaacagtatcacactgcaaaacaacttataactaaaaa    250

seq          42                                                              41

seq          251 atgagtatgaaataaaaaaatattttttgctctacatttaatttacctttt    300

seq          42                                                              41

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seq	1101	tccaaatcttagctttaccccttttagaaacttatcctgattataatgaag	1150

Needle

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seq	42		41
seq	1151	ctctaaaagaaaaagaatgttttacttataaattaggagaagaatttata	1200
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seq	1201	aaagctggtaagaattgggtatggggaggggtatcacaatttatattcaa	1250
seq	42		41
seq	1251	agatgttcctaggttgaagagagagtttgagaaaggggaataa	1293
seq	42		41

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